

**REMARKS**

**Summary Of The Office Action & Formalities**

**Status of Claims**

Claims 1, 2, 4, 5 and 7-11 are all the claims pending in the application. By this Amendment, Applicant is amending claims 1, 4 and 7. No new matter is added.

**Additional Fees**

Submitted herewith is a Petition for Extension of Time with fee.

**Drawings**

Applicant thanks the Examiner for acknowledging and accepting the drawing filed on August 3, 2009.

**Claim Rejections - § 112**

Claims 1, 2, 4, 5, 7 and 8 are rejected under 35 U.S.C. § 112, second paragraph, for the reason set forth at page 2 of the Office Action.

Applicant is amending the claims to overcome this rejection.

**Art Rejections**

Claims 1, 2, 5 and 7-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tomaka (US 6,651,844) in view of Rocci (US 6,138,669).

Applicant respectfully traverses.

**Claim Rejections - 35 U.S.C. § 103**

*Claims 1, 2, 5 and 7-11 Over Tomaka (US 6,651,844) in view of Rocci (US 6,138,669).*

In rejecting claims 1, 2, 5 and 7-11 over Tomaka (US 6,651,844) in view of Rocci (US 6,138,669), the grounds of rejection state:

Regarding claims 1, 2, 5, and 7-11, Tomaka discloses a fluid product nasal atomizing and spraying device (10) comprising a pump that operates without piezoelectric, electrostatic spraying mechanisms or propellant gas (column 3, lines 17-18), a spray head (20) (fig. 2) to actuate the pump manually (column 3, lines 27-28), and a dispensing detection means (40) to detect that a product does has been dispensed. The detection means (40), which is connected to electronic means (52) to process the signal, outputs a signal to inform the user that a dose has been dispensed by the pump (column 5, lines 8-12). Tomaka further discloses the pump being connected to a spraying orifice (16a) through an expulsion channel (16) (fig. 2), but does not disclose the detection means being provided in the expulsion channel. Rocci teaches a dose counter for a nasal device (column 3, lines 44-50) with a detection means in the form of a pressure sensor (12) provided in an expulsion channel (7) (fig. 3) and adapted to detect the passage of a product in the expulsion chamber due to a pressure difference at the time that a product dose is sprayed (column 5, lines 118). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the nasal spray device of Tomaka with a detection means provided in an expulsion chamber as taught by Rocci in order to provide the advantage of fewer miscounts, as taught by Rocci (column 2, lines 44-47).

Office Action at page 3.

Responding in part to Applicant's previous arguments, the Examiner states:

Applicant's arguments filed 8/3/09 have been fully considered but they are not persuasive. Applicant's arguments concerning the sensor of Rocci not being operable in the device of Tomaka on the grounds that no pressure burst exist, is not persuasive since in order for a fluid to travel through a passage; such as the passage of Tomaka, a pressure difference must exist therefore the sensor of Rocci would be able to sense the dispensing of medicament in the device of Tomaka.

Office Action at page 4.

In order to find a claim obvious, the Examiner must determine that all the limitations would be met in the alleged modified device. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385,

165 USPQ 494, 496 (CCPA 1970). In addition to this all limitations requirement, the Examiner must articulate convincing rationale for why one skilled in the art would have carried out the asserted modification. Indeed, the Supreme Court in *KSR v. Teleflex* left undisturbed the requirement that the Examiner must present “a convincing line of reasoning supporting a rejection.” MPEP § 2144. Furthermore, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007).

For at least the reasons discussed below, these two requirements have not been adequately satisfied.

First, regarding the all limitations requirement, the Examiner’s position is essentially that Tomaka generates sufficient pressure differential that can be detected by the sensor of Rocci. However, nowhere is this technical conclusion supported. Rather, the grounds of rejection assume that *any* amount of pressure differential would suffice. However, as explained in Applicant’s previous response, the sensor of Rocci is ***specifically designed for a MDI device***—that is devices that use a propellant with a metered dose valve to deliver the dose. Such device produce a pressure burst that is detected by the sensor. On the other hand, the device disclosed in Tomaka does not use a propellant. Thus, even if one were to modify the device of Tomaka to include the sensor of Rocci, it is not evident that the sensor would operated as claimed.

Moreover, given that the sensor of Rocci is ***specifically designed for a MDI device***, it would not have been obvious in the first place to modify the device of Tomaka to include ***only*** the sensor from Rocci and without further modifying the device of Rocci to include the

propellant and valve. There is no rationale for lifting only the sensor from Rocci and adapting it to the device of Tomaka.

To be sure, the grounds of rejection do state that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the nasal spray device of Tomaka with a detection means provided in an expulsion chamber as taught by Rocci in order to provide the advantage of fewer miscounts, as taught by Rocci (column 2, lines 44-47).”

However, what this stated rationale does not take into account is that the device of Tomaka *already includes a mechanism for ensuring no miscounts.*

In fact, the disclosure and subject matter of the claims of Tomaka are specifically directed to a mechanism for *accurately counting* sprays. *See e.g.*, Tomaka at 1:4-8 and 51-64. Nowhere in the prior art is there an indication that the mechanism in Tomaka is deficient or inadequate in any way. In addition, one skilled in the art would not have found it obvious to replace the mechanism of Tomaka with the one of Rocci, since the latter is more complex and expensive. Rather, it is *Applicant’s disclosure* that teaches the benefit of *detecting* the passage of product in the expulsion channel to confirm a dose has been emitted.

Furthermore, the grounds of rejection do not explain why one skilled in the art, looking for a system informing the user that the dose of product has actually been dispensed from a pump operating without propellant gas, would even look into Rocci to find a solution, which is exclusively limited to MDI systems, that is systems containing propellant in a pressurized canister and using a metered dose valve. *See, e.g.*, Rocci at 1:15-31.

In all cases, Rocci makes clear that the sensor is used in MDI applications – systems having propellant gas in a pressurized container operating with a metered dose valve.

In Tomaka, there is a sound generator and a count decrement indicating to the user that the actuating button has been properly depressed. *See, e.g.,* Tomaka, at 5, lines 10-12. The sound generator and count decrement are employed in a pump operating without propellant.

Thus, one basic difference between the claimed invention and Tomaka is the dispensing detection system. Whereas in Tomaka it is the correct actuation of the actuating button that is indicated, in the claimed invention, it is the effective dispensing of the product passing through the expulsion channel that is detected.

Again, as explained above, it would not have been obvious to a person skilled in the art to consider Rocci to replace Tomaka's sound generator by a dispensing detection system, especially given that the technical field of MDI's, operating with pressurized propellant gas, is fundamentally different from the technical field of pumps operating without such propellant. Indeed, the dispensing properties created during dispensing by an MDI are different from those created by a pump operating without propellant. Furthermore, there is no indication that the counting and sound generating device of Tomaka is in anyway inadequate. A person skilled in the art thus would have no reason to believe that he may find in the MDI field a solution operating in the pump field.

In view of at least the foregoing, the Examiner is requested to reconsider and withdraw the rejection.

#### **Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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